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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,351	03/29/2004	Gary Durack	MTC 2001.1 (37-21(53260)B	2698
321	7590	03/03/2008	EXAMINER	
SENNIGER POWERS LLP ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			WALLENHORST, MAUREEN	
			ART UNIT	PAPER NUMBER
			1797	
			NOTIFICATION DATE	DELIVERY MODE
			03/03/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No. 10/812,351	Applicant(s) DURACK ET AL.	
	Examiner Maureen M. Wallenhorst	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-64 and 81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45,47-49,53-60,62-64 and 81 is/are rejected.
- 7) ☒ Claim(s) 46,50-52 and 61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/17/07</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "said" on line 5 and "comprising" on line 11 of the amended abstract received on December 14, 2007. Correction is required. See MPEP § 608.01(b).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. Claims 45, 47-49, 53-60, 62-64 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potts et al (US 2003/0078703, submitted in the Information Disclosure Statement filed on December 17, 2007) in view of Hoffman et al (WO 01/29538).

Potts et al teach of a multi-channel cytometry analysis system that comprises a plurality of cytometry instruments 14a-14n adapted to operate in parallel. Any number of cytometry instruments 14 can be included in the system, and all are connected to an integrated platform comprising a common processor in the form of a database server 12. The database server 12 is in communication with a database 16. See Figure 1 in Potts et al. Potts et al teach that each of the cytometry instruments 14 can be a conventional apparatus such as a flow cytometer, a fluorescence-activated cell sorter or a laser scanning cytometer. Raw data collected by the cytometry instruments 14 such as detected scattered light and fluorescence is received by the common processor or database server 12 substantially continuously, and the server 12 processes the output signals from the instruments 14. For example, the light intensity values measured for a single cellular event in each of the cytometry instruments 14 is transferred to the integrated platform of the database server 12, along with experimental data concerning operating parameters of the cytometry instruments. The database server 12 performs computations with the light intensity values and the experimental data. See Figure 1 and paragraphs 0021-0022, 0025 and 0026 of Potts et al. Potts et al fail to teach that each of the cytometry instruments contains a sensor therein to generate a time-varying output signal indicative of at least one characteristic of the particles or cells in a stream of fluid as the stream is interrogated by a beam of electromagnetic radiation.

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Hoffman et al teach of a flow cytometer apparatus and a method for examining particles such as blood or sperm cells using the apparatus. The apparatus 100 comprises a flow cell 104 in which a sheath fluid surrounds a cell stream, and the combined sheath fluid and cell stream exits the flow cell 104 via an opening in a capillary 109 as a sample stream 110. The sample stream remains intact until breaking off into droplets at the droplet break off point 112. The distance from the opening in the capillary 109 at which the droplet break off point 112 occurs, and the frequency or rate at which the droplets are formed are governed by the fluid pressure, as well as the amplitude and frequency of oscillation of an oscillating device 114. The oscillating device 114 is connected to an alternating voltage source 116 whose output voltage amplitude, frequency and phase is controlled by a controller 118 which can be a microprocessor or other controlling device. The amplitude of the alternating voltage signal output by alternating voltage source 116 can be increased or decreased by controller 118 to increase or decrease the distance from opening 110 at which the droplet break off point 112 occurs. Also, the frequency of the alternating voltage signal output by alternating voltage source 116 can be increased or decreased by controller 118 to increase or decrease the rate at which droplets of sample fluid are formed at the droplet break off point 112. The flow cytometer apparatus 100 comprises a plurality of cell evaluation assemblies 120. Each cell evaluation assembly comprises a laser 122, an LED assembly 124 having a lens 126, an optional filter 128, a first and second dichroic mirror 130, 132, a first detector 134 having filter 136, and a second detector 138 having a filter 140. The laser 122 can be any type of known laser such as a diode laser, semiconductor laser, etc, which is controlled by the controller 118 to emit laser light which radiates onto the flow stream 110. The detectors 134, 138 can each be photomultiplier tubes or any other suitable type of light detecting

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device. The detectors 134 and 138 are positioned within the path of light exiting from the immersion lens arrangement 111 so that the lens arrangement can focus an image of the sample stream 110 onto the filters 136, 140. The filters permit fluorescent light from the cells, which have been excited by light from LED assembly 124, to pass detector 134, and filter 140 permits fluorescent light emitted from the cells which have been excited by light from laser 122 to pass to detector 138. The light emitted by the laser 124 radiates onto the flow stream 110 at a point which is about 100 microns upstream of the point at which the light emitted by LED 125 radiates onto flow stream 110. The flow cytometry units 120 can include any number of lasers, dichroic mirrors, detectors and LED assemblies, which can be arranged to evaluate different types of particles and different characteristics of the cells, such as size, complexity and granularity. In addition, although Figure 1 in Hoffman et al only depicts a single cell evaluation assembly 120, the flow cytometry apparatus 100 can employ any number of cell evaluation assemblies 120 having one or more lasers, one or more LED assemblies, one or more mirrors and one or more detectors. The controller 118 receives time-varying signals from each of the flow cytometry units 120 in a continuous manner, and processes the signals in order to analyze and sort the blood or sperm cells. The controller 118 also serves to control the lasers 122, detectors 134 and 138, and the LED assemblies. The detectors 126 and 128 each convert the light they receive into electrical signals, which are interpreted by controller 118 as representing a characteristic of the cells in the sample fluid at a given sampling time. The controller 118 can also control a charging unit 184 to charge cells of interest in accordance with their detected characteristic, so that the cells can be sorted by deflection plates 186 and 188, which serve to sort cells of interest into different collection vessels 190, 192 and 194. The cells in the sample reservoir 106 are treated

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with a stain prior to sorting in the apparatus so that the cells fluoresce when irradiated with light of a certain wavelength. Hoffman et al also teach that the lasers and LED assemblies in the flow cytometry units 120 can utilize an epi-illumination configuration. See Figures 1-2 and pages 8-12, 14 and example 1 on page 21 of Hoffman et al.

Based upon the combination of Potts et al and Hoffman et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include in each of the multiple cytometry instruments 14 taught by Potts et al a sensor to generate a time-varying output signal indicative of at least one characteristic of the particles or cells in a stream of fluid as the stream is interrogated by a beam of electromagnetic radiation since Potts et al disclose that the cytometry instruments 14 are any conventional type of flow cytometer or fluorescence activated cell sorter, and Hoffman et al teach that one type of conventional flow cytometer or fluorescence activated cell sorter contains therein one or more lasers to produce an electromagnetic beam of radiation towards a stream of cells to be sorted and a sensor or detector assembly that generates a time-varying signal indicative of at least one characteristic of the cells in the stream as the stream is interrogated by the beam of radiation. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention since one of skill in the art could easily use the conventional flow cytometer taught by Hoffman et al as each of the instruments in the parallel arrangement of cytometry instruments of the multi-channel system disclosed by Potts et al.

Potts et al also fail to teach that the plurality of cytometry instruments are interchangeable modules in the common housing of the analysis system, and fail to teach that the processor or database server 12 is operable to output the rate at which particles are separated in the cytometry instruments, the decision boundary used by each instrument to discriminate between particles, and the operation of one instrument in relation to another instrument. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to render each of the cytometry instruments taught by Potts et al as an interchangeable module in the common housing of the analysis system so as to allow one of the instruments to be replaced when it is not working properly without having to replace or shut down the entire analysis system, thus allowing a more efficient operation of the system. It also would have been obvious to one of ordinary skill in the art to operate the processor or database server 12 taught by Potts et al to output the rate at which particles are separated in each cytometry instrument, the decision boundary used by each instrument to discriminate between particles, and the operation of one instrument in relation to another unit since these are common control parameters in a flow cytometer controlled by a processor such as a database server that provide an indication to an operator of the cytometer as to whether it is operating properly to sort particles and the criteria used to sort the particles.

6. Claims 46, 50-52 and 61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a multi-channel particle sorting apparatus comprising a plurality of flow cytometry units, wherein each separate unit comprises its own cell stream where the cells are individually

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sorted using a jet-in-air droplet technique, and wherein a **common source of electromagnetic radiation** is used for exciting fluorescently-labeled cells in each of the separate cell streams in each of the separate sorting units.

7. Applicant's arguments with respect to claims 45-64 and 81 have been considered but are moot in view of the new ground(s) of rejection.

The abstract submitted in the response received on December 14, 2007 is objected to for the inclusion of legal phraseology. See paragraph no. 2 above. The previous rejections of the claims under 35 USC 102(b) as being anticipated by Hoffman et al and under 35 USC 103 as being obvious over Hoffman et al made in the last Office action mailed on June 15, 2007 have been withdrawn in view of Applicants' persuasive arguments. However, the claims are now rejected under 35 USC 103 as being obvious over Potts et al in view of Hoffman et al for the reasons given above in paragraph no. 5. This Office action is being made final even though a new ground of rejection has been made since the reference to Potts et al was submitted in an Information Disclosure Statement filed on December 17, 2007 after the mailing of a first Office action, and with the fee set forth in 37 CFR 1.17(p). Where the information is submitted after the mailing of a first Office action with a fee, the Examiner may use the information submitted and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the Examiner. See MPEP 706.07(a).

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

February 20, 2008

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797